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AMPHASTAR PHARMACEUTICALS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

AMPHASTAR PHARMACEUTICALS, INC., INTERNATIONAL MEDICATION SYSTEMS, LTD., Plaintiffs vs. MOMENTA PHARMACEUTICALS, INC., SANDOZ PHARMACEUTICALS, INC., Defendants.	Civil Action No. 5:15-CV-01914 **COMPLAINT FOR VIOLATIONS OF THE SHERMAN ACT; VIOLATIONS OF THE CARTWRIGHT ACT; UNFAIR BUSINESS PRACTICES** Judge: Courtroom:

JURY TRIAL DEMANDED

Plaintiffs Amphastar Pharmaceuticals, Inc. and International Medication Systems, Ltd. (collectively "Plaintiffs") allege as follows:

THE PARTIES

1. Plaintiff Amphastar Pharmaceuticals, Inc. ("Amphastar") is a specialty and generic pharmaceutical company located in Rancho Cucamonga, California. Amphastar develops, manufactures, and markets technically complex proprietary and generic drug products and active pharmaceutical ingredients ("APIs") at its state-of-the-art facilities. Amphastar, either directly or through its distributors, has long-standing relationships with all the major group purchasing organizations ("GPOs") and drug wholesalers in the United States, which enables Amphastar to rapidly introduce new products and quickly establish significant market share. Amphastar currently manufactures and sells a generic version of the drug enoxaparin.

2. Plaintiff International Medication Systems, Ltd. ("IMS") is a wholly-owned subsidiary of Amphastar with its principal place of business in South El Monte, California. IMS manufactures sterile injectable products that are sold in a variety of delivery systems, including pre-filled syringes and vials. IMS also manufactures the API for Amphastar's generic enoxaparin.

3. Defendant Momenta Pharmaceuticals, Inc. ("Momenta") is a Delaware corporation with a principal place of business at 675 West Kendall Street, Cambridge, Massachusetts 02142. Momenta is the assignee of at least one United States patent that Momenta alleges relate to methods of analyzing enoxaparin.

4. Defendant Sandoz, Inc. ("Sandoz") is a Colorado corporation with a principal place of business at 506 Carnegie Center, Princeton, New Jersey 08540. Sandoz is the distributor of a generic enoxaparin product that it markets and sells throughout the

United States. Sandoz and Momenta have entered into a profit-sharing contractual relationship, which includes an exclusive license of the Momenta patent as further alleged herein. Defendants Momenta and Sandoz will be referred to collectively as "Defendants."

JURISDICTION AND VENUE

Subject Matter Jurisdiction

5. Plaintiffs and Defendants are engaged in interstate commerce and in activities substantially affecting interstate commerce. They are engaged in a regular, continuous, and substantial flow of interstate commerce. Defendants are competitors of Plaintiffs in connection with the sale of generic enoxaparin in the United States. The drug enoxaparin is sold in all fifty states and has a substantial effect upon interstate commerce.

6. This Court has federal question subject matter jurisdiction over the claims of this Complaint under the Sherman Act, 15 U.S.C. §§ 1-2, the Clayton Act, 15 U.S.C. § 15(a), 28 U.S.C. § 1331, and as a civil action relating to regulation of monopolies, 28 U.S.C. § 1337.

7. This Court has federal question subject matter jurisdiction over the claims of this Complaint under the Clayton Act, 15 U.S.C. §§ 12–27, 29 U.S.C. §§ 52–53, as a federal law, 28 U.S.C. § 1331, and as a civil action relating to regulation of monopolies, 28 U.S.C. § 1337.

8. This Court further has subject matter jurisdiction because the parties are diverse and the amount in controversy exceeds $75,000. 28 U.S.C. § 1332. Amphastar and IMS are citizens of California; Momenta is a citizen of Massachusetts; Sandoz is a citizen of New Jersey. 28 U.S.C. § 1332(c)(1).

9. This Court further has supplemental jurisdiction under 28 U.S.C. § 1367 on Plaintiffs' claim for violations of the Cartwright Act, found at California Business and Professions Code § 16720 *et seq.*, because the claim is "so related to claims in the action within such original jurisdiction that [it] form[s] part of the same case or controversy under Article III of the United States Constitution."

10. Further still, this Court has supplemental jurisdiction under 28 U.S.C. § 1367 on Plaintiffs' claim for violations of California Business and Professions Code § 17200, because the claim is "so related to claims in the action within such original jurisdiction that [it] form[s] part of the same case or controversy under Article III of the United States Constitution."

Personal jurisdiction

11. This Court has personal jurisdiction over Defendants because Defendants knowingly transact a large volume of business in California in the form of sales of pharmaceuticals, including generic enoxaparin. Further, Defendants directed their actions toward Plaintiffs in this district and succeeded in causing competitive injury to Plaintiffs in this district.

Venue

12. Venue is proper in this Court because this Court has personal jurisdiction over Defendants. 28 U.S.C. § 1391(b). Further, Defendants directed their actions toward Plaintiffs in this district and succeeded in causing competitive injury to Plaintiffs in this district.

13. Venue is further appropriate in this Court because Defendants conduct a substantial amount of business in this judicial district. 28 U.S.C. § 1391(b).

14. Venue is further appropriate in this Court because Plaintiffs' principal place of business is located within this judicial district. 28 U.S.C. § 1391(c).

FACTS COMMON TO ALL CLAIMS

The Market for Enoxaparin Prior to Generic Entry

15. This case involves the anticoagulant drug "enoxaparin." Enoxaparin is a low molecular weight heparin ("LMWH"). In medicine, enoxaparin is used in the prevention and treatment of deep vein thrombosis (including inpatient treatment of acute deep vein thrombosis with or without pulmonary embolism, and outpatient treatment of acute deep vein thrombosis without pulmonary embolism), and in the treatment of myocardial infarction, including certain specific myocardial infarction treatments (e.g., acute ST-segment elevation myocardial infarction). Other LMWHs are prepared by different processes than enoxaparin and have distinct physical, chemical, and biological properties, and they are not considered as clinically equivalent to enoxaparin. Enoxaparin is the most popular and widely prescribed LMWH due mainly to its physical, chemical, and biological properties and it generates the largest sales. No other anticoagulant drug is a close substitute for enoxaparin.

16. Sanofi-Aventis ("Aventis") originally introduced enoxaparin to the United States in 1995 under the brand name Lovenox®, after obtaining approval from the Food and Drug Administration ("FDA"). Lovenox® became a huge commercial success for Aventis, generating billions in revenue in the United States. Prior to entering the United States market, Aventis filed an application on June 26, 1991, for a United States patent purporting to cover Aventis's Lovenox® product. Aventis's patent eventually issued on February 14, 1995 as United States Patent No. 5,389,618

(the "'618 patent"). Aventis listed the '618 patent in the FDA's Orange Book as being applicable to its Lovenox® product.

17. An applicant seeking the right to market a generic drug in the United States may file an Abbreviated New Drug Application ("ANDA") with the FDA. An ANDA applicant must establish to the FDA's satisfaction that the generic drug meets the FDA's "sameness" standard as compared to the brand drug. Compliance with FDA rules, regulations and requirements is mandatory for the sale of drug products in the United States.

18. Amphastar filed an ANDA to sell a generic version of enoxaparin in the United States on March 4, 2003. In its ANDA, Amphastar contended that Aventis's '618 patent was invalid and unenforceable. Amphastar was the first to file with the FDA for the FDA's approval to sell a generic version of enoxaparin in the United States, and Amphastar was the first generic applicant to receive acknowledgement of "sameness" by the FDA for generic enoxaparin, dated November 2, 2007. Amphastar received FDA approval to sell enoxaparin on September 19, 2011.

19. Teva Pharmaceuticals, Inc. followed Amphastar, and on June 24, 2003, filed an ANDA seeking FDA approval to sell generic enoxaparin in the United States. Teva was the second filer to seek FDA approval to sell a generic version of enoxaparin. Teva received FDA approval to sell enoxaparin on June 23, 2014.

20. Defendant Sandoz filed an ANDA on August 26, 2005, two and a half years after Amphastar's filing. Sandoz was the third filer for a generic version of enoxaparin. Sandoz received FDA approval to sell enoxaparin on July 23, 2010. Among other collaborative aspects of their relationship in connection with their generic enoxaparin product, Sandoz is the ANDA owner and Momenta is Sandoz's contract laboratory.

21. On August 4, 2003, Aventis sued Amphastar and Teva, alleging infringement of the '618 patent. On February 8, 2007, Amphastar cleared the way for generic competition by successfully establishing that Aventis's '618 patent was unenforceable due to inequitable conduct. The Federal Circuit affirmed that decision on May 14, 2008.

22. From the time Aventis began selling Lovenox® in the United States until approximately late July 2010, Aventis was the sole source for enoxaparin in the United States because the FDA had not approved a generic version of Lovenox®.

Defendants' Intent to Be the Sole Source of Generic Enoxaparin in the United States

23. For purposes of the claims alleged herein, the relevant product market was—and is—the market for generic enoxaparin, or in the alternative, enoxaparin. Between generic and brand enoxaparin, consumers who are price-sensitive primarily purchase generic enoxaparin, and would view another generic, as opposed to the brand, as a reasonable substitute. Generic manufacturers primarily compete against each other for sales. Due to purchasing structures in different channels of trade, if a generic is commercially available, some distributors will purchase and supply only generic enoxaparin. Generic manufacturers regard the pricing of other generic manufactures as directly affecting their pricing. The relevant geographic market was—and is—the United States.

24. On or about November 1, 2003, Defendants entered into a Collaboration and License Agreement ("Collaboration Agreement") for the development and commercialization of enoxaparin sodium injection in the United States. The Collaboration Agreement heavily incentivized Defendants to obtain and maintain themselves as the sole source of generic enoxaparin in the United States.

25. The Collaboration Agreement contained financial incentives, which included among other things, certain milestone payments for Defendants to be the sole provider of generic enoxaparin in the United States. Momenta's President and CEO, Craig Wheeler, publicly stated regarding the Collaboration Agreement that "if you look at the structure of the deal, the company is heavily, heavily incentivized to be a *sole* generic in the marketplace."

26. Under the terms of the Collaboration Agreement, Sandoz was obligated to pay higher amounts of profit share or royalty payments to Momenta so long as there were no third-party competitors marketing a generic enoxaparin. As contemplated by the Collaboration Agreement, provided that a generic monopoly existed, Momenta would receive a profit share payment from Sandoz significantly higher than a royalty payment. The Collaboration Agreement also provided that Momenta would receive no less than a 45% share of all profits earned by Sandoz's sales of its generic enoxaparin so long as Defendants were the sole source of generic enoxaparin in the United States.

27. The Collaboration Agreement also obligated Sandoz to make various milestone payments, which were contingent upon no other generic enoxaparin products entering the market (*i.e.*, contingent upon developing and maintaining a generic monopoly). For example, on or about July 23, 2011, Momenta received a $10 million milestone payment from Sandoz in recognition of completing a full year of sales without an additional generic enoxaparin product entering the market.

28. Further, the compensation from Sandoz to Momenta would be substantially higher so long as Defendants' generic enoxaparin remained the sole generic enoxaparin product available. For example, because there were no competing generic enoxaparin products on the market for at least one year following Defendants' launch

of their generic enoxaparin, the compensation from Sandoz to Momenta was double or triple that which Momenta would receive if there had been market entry by a competitor.

29. Sandoz, for its part, also enjoyed significantly higher revenues and profits under a profit sharing arrangement rather than a royalty payment for the simple reasons that during the time there were no other generic enoxaparin competitors on the market, Sandoz commanded a much higher price for its generic enoxaparin, and no competing sales were diverted to any competitors. Sandoz, in fact, did maintain a high price for Defendants' generic enoxaparin product—a price that was very close to Aventis's price for its Lovenox® brand product—for the entire duration of time that Defendants marketed the sole generic enoxaparin product. During the first year, sales of Defendants' generic enoxaparin product exceeded one billion dollars. Sandoz's ability to maintain a high price for Defendants' generic enoxaparin was of paramount importance to Sandoz, and it was critical to Sandoz to ensure generic competitors were blocked from entering the market.

30. The terms of the Collaboration Agreement created a strong financial incentive for Defendants to obtain and maintain a monopoly in the relevant market for as long as possible.

31. The Collaboration Agreement also exclusively licensed Momenta's patents to Sandoz, which were intended to be used by Defendants to exclude competition. Among the licensed patents was United States Patent No. 7,575,866 (the "'886 patent"). Momenta filed the application that matured into the '886 patent on March 11, 2003, and the '886 patent issued on August 18, 2009. Among the named inventors was Momenta's Dr. Zachary Shriver.

Defendants' Deception of the USP Standards Setting Organization to Obtain a Generic Monopoly

32. At least by 2007, Aventis had requested that the United States Pharmacopeial Convention ("USP") adopt criteria for enoxaparin that included a standardized test that Aventis had developed for determining such criteria, namely that 15 to 25% of the carbohydrate chains in enoxaparin had a 1,6-anhydro ring structure on one of their terminal ends. In or around February 2007, or at least by that time, the USP had begun work on a proposed standard for enoxaparin, including work on a test method proposed by Aventis. Aventis's proposed standard became known as USP Method <207>.

33. The USP is a scientific nonprofit organization that sets standards for identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements that are manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the FDA. USP standards are recognized and required under federal law. For example, the FDA enforces USP standards by requiring that any pharmaceutical product comply with the USP monograph for that drug product. *See* 21 U.S.C. § 351(b). Further, "[c]ompliance with a USP-NF monograph, if available, is mandatory."

34. As a public standards-setting organization, the USP has an express policy of impartiality and of not favoring one manufacturer over another in setting its standards. "USP will hold open meetings and publish standards impartially. USP will not provide . . . standards-setting activities, in a manner that will allow any stakeholder to have an undue advantage over another stakeholder." "Consistent with and in furtherance of this mission, USP is committed to doing all it reasonably can to assure that USP-NF standards and related methods are developed through an objective, independent, science-based process, and that the resulting official compendial standards not have the

effect of favoring any manufacturer over others or putting any FDA-approved product out of compliance. The USP attempts to maintain independence and impartiality, as it is critical to the integrity and credibility of its standard-setting activities."

35. To ensure impartiality and its policy of not favoring any one manufacturer over another, the USP maintains a strict Code of Ethics that applies to all members and participants of USP committees. The USP develops these standards through "members" or "participants" of various expert panels and committees, often scientists in the field relevant to the standard being developed. Each member and participant agrees to the USP's Rules and Procedures of the Council of Experts, which include specific rules on conflicts of interest. Each individual or entity involved in the standard-setting process has a duty to ensure that they remain free of any actual or perceived conflicts of interest in the performance of their duties. The conflict-of-interest rules place a duty on each member to submit to the USP a statement disclosing all interests that could result in a conflict of interest, including intellectual property rights. In the event that a conflict of interest arises, it is the duty of the member to disclose the conflict of interest to the USP. The USP will not permit a member to be present for the final discussion, deliberation, or vote on the issue on which he or she has a conflict of interest.

36. It is common practice for USP Staff to review USP conflict of interest policies at the beginning of USP panel meetings.

37. Zachary Shriver, who was an employee and director at Momenta during the relevant time period, served as Momenta's representative on USP's Heparin Ad Hoc Advisory Panel and Low Molecular Weight Heparins Expert Panel, which oversaw the development and approval of USP's enoxaparin standard. In spite of his association with Momenta at the time, Dr. Shriver—and Momenta whom he represented on the

panel—owed the USP a duty to disclose any and all information relevant to the USP's adoption of the enoxaparin standard. Dr. Shriver and Momenta were well aware of their duty to the USP and the USP's policy not to favor one manufacturer over another. In fact, Dr. Shriver who was Senior Director of Research Analytics at Momenta, concurrently and simultaneously represented both Momenta as well as USP (and thus the public interest) during the time that Dr. Shriver participated in the USP panel discussions and the ultimate adoption of USP Method <207>.

38. Sandoz also participated in panel discussions and owed the USP a duty to disclose any and all information relevant to the USP's adoption of USP Method <207>.

39. During the USP's consideration of USP Method <207>, Defendants and Dr. Shriver learned that Aventis had a pending patent application, the claims of which, if issued, would read on USP Method <207>. Defendants objected to Aventis having a patent that covered a standardized USP test, contending that the test, once adopted, should be free for anyone to use. Defendants insisted that the USP require Aventis to expressly abandon the patent application so that there would be no doubt that any member of the public could practice USP Method <207>. Defendants were aware at the time that the USP had a policy of not favoring one manufacturer over another. Defendants were aware at the time that the USP would be disinclined to adopt a standard test method that was covered by one company's patent, which could prohibit the free public use of the USP's adopted standard and method.

40. Defendants were very familiar with USP Method <207> and the USP's conflict of interest policies. On or about November 14, 2008, USP held a meeting of the Heparin Ad Hoc Advisory Panel that was considering the USP's adoption of USP Method <207>. At the beginning of the meeting USP Staff member, Mr. Van Hook, gave a presentation to those in attendance of USP's rules of conflict of interests. The

attendees were specifically advised that their "[p]osition as a member should not be used to benefit one's own interest, or the interest of his or here company." Defendant Momenta presented a detailed analysis of USP Method <207> including commenting on specific enzymes, columns, reagents and procedures used in the method. Dr. Shriver was in attendance during the November 14, 2008 USP meeting.

41. Also during the November 14, 2008 Heparin Ad Hoc Advisory Panel meeting, the USP Staff reported: "USP has had successful correspondence with the company [Sanofi-Aventis] that may have patents that may pertain to the test or related tests. The company has reported that it will allow the one patent that may cover the method to lapse. ***As such USP is not aware of any patent issue that may cover the test.*** The AP may proceed with the use of the test as planned."

42. Though in attendance at the November 14, 2008 Heparin Ad Hoc Advisory Panel meeting, neither Momenta nor Dr. Shriver advised the USP of Defendants' pending patent application. Other than Defendants' Dr. Shriver, no one else serving on the USP panel for setting standards for enoxaparin knew that Defendants had a patent application that they would use to block the use of USP Method <207> after the '866 patent issued.

43. Having obtained Aventis's abandonment of Aventis' pending patent application—and being unaware of Momenta's pending application due to its non-disclosure by Defendants— in December 2009, the USP approved and adopted USP Method <207>. Once the USP adopted USP Method <207>, it became the official test method that the FDA required of Amphastar to test for its enoxaparin in order to obtain and maintain its generic enoxaparin approval.

44. On or about March 4, 2011, the USP held a meeting of the USP Low Molecular Weight Heparins Expert Panel. Dr. Ishan Capila appeared on behalf of Momenta as an

Expert Panel member. Dr. Shriver also attended as an Expert Panel member. The USP staff once again reviewed USP's conflict of interest policy and informed the panel members that conflicts of interest must be disclosed. Again, neither Momenta, Dr. Capila, nor Dr. Shriver disclosed their then issued '886 patent.

45. On or about April 20-21, 2011 the USP held another meeting of the USP Low Molecular Weight Heparins Expert Panel. Again Dr. Capila and Dr. Shriver attended as Expert Panel members. Again, USP Staff reviewed the USP conflicts of interest policy including the requirement that Expert Panel members disclose any conflicts of interest. The USP Staff advised the Expert Panel members: "All Counsel of Expert members, those on either the EC or EP, must declare their conflicts of interest and must sign a confidentiality agreement. Due to the nature of work of the Council of Experts, especially in the biologics and biotechnology area ***there are potential antitrust and biosimilar issues that the EP should keep in mind throughout its work***." Again, despite this warning, neither Momenta, Dr. Capila, nor Dr. Shriver advised the USP of Momenta's then-issued '886 patent.

Defendants' Wrongful Enforcement Of Their Patent Against Use Of The USP Standard Method

46. Defendants were the first to obtain FDA approval for a generic version of enoxaparin. The FDA granted final approval for Defendants' ANDA on or about July 23, 2010, and immediately thereafter, Defendants began selling and shipping generic enoxaparin to customers in the United States. At the time, and until Amphastar received FDA approval, Defendants were the sole source of generic enoxaparin in the United States and held a monopoly in the relevant market. Alternatively, Defendants obtained a dangerous probability of monopolizing the relevant market.

47. According to the FDA, on average, the first generic competitor prices its product only slightly lower (about 94%) than the brand name manufacturer. However, market entry by a second generic manufacturer reduces the average generic price to nearly half the brand name price (about 52%). As additional generic manufacturers enter the market with their competing products, prices continue to fall, but more slowly. For products that garner a large number of generic market entrants, the average generic price falls to 20% (and sometimes even lower) of the branded price. These marketing trends are based upon a well established study conducted by the FDA derived from an extensive *IMS Health* retail sales database and demonstrate why the Defendants sought to wrongfully maintain a monopoly. Defendants' conduct kept the price of enoxaparin artificially high, which cost the consumers, including the state and federal governments, billions of dollars in overcharges.

48. Beginning in July 2010 and continuing until some time into 2012, Aventis and Defendants each had some degree of market power. That is, Aventis was able to charge a higher price for branded Lovenox®, and Defendants were able to charge a higher price for its generic enoxaparin, than either of them would have been able to charge had there been additional sellers of generic enoxaparin.

49. On September 19, 2011, the FDA approved Amphastar's ANDA to sell generic enoxaparin in the United States. As a condition for approval, the FDA specified that Amphastar needed to establish on a batch-by-batch basis that its generic enoxaparin contains between 15 and 25 percent of the 1,6-AS. Upon approval, the FDA instructed Amphastar to comply with the USP compendium for enoxaparin, including USP Method <207>. In particular, as required by the USP Monograph for enoxaparin, Amphastar was required to establish that: "About 20 percent of the material contains a 1,6-anhydro derivative on the reducing end of the chain, the range being between 15 and 25 percent."

50. On September 21, 2011, two days after Amphastar received FDA approval to market generic enoxaparin in the United States, and in direct conflict with the position that USP Method <207> should be free to be used by anyone, Defendants sued Amphastar, wrongfully enforcing their patent against Amphastar's use of USP Method <207>. Notably, Defendants enforced their patent and sued Amphastar, despite the fact that Momenta was the third generic filer, and despite the fact that the first filer (Amphastar) already had invalidated Aventis's Orange Book patent.

51. In their Complaint, Defendants represented to the court: "The FDA requires a generic manufacturer to include in its manufacturing process the analysis of each batch of its enoxaparin drug substance to confirm that its manufacturing process results in the production of oligosaccharides that include defined relative amounts of a non-naturally occurring sugar that includes a 1,6-anhydro ring structure."

52. Defendants represented in other pleadings that the FDA also requires generic manufacturers of enoxaparin to ensure that each batch complies with the standards for identity enumerated in the USP Monograph for enoxaparin.

53. Defendants further represented that the USP Monograph for enoxaparin is an official written standard that provides the definition of enoxaparin and the requirements that a maker of enoxaparin must satisfy in order to ensure the drug product's quality, strength, and purity.

54. Still further, Defendants represented that the United States Pharmacopeia is the standard-setting body for drugs sold in the United States and that the USP monographs are enforced by the FDA.

55. Defendants further contended that the claims of the ’886 patent covered the USP Method <207>.

56. Defendants admitted that Amphastar’s market entry is certain to cause an immediate and substantial reduction in Sandoz’s price for enoxaparin and Sandoz’s market share.

57. Upon filing their complaint against Amphastar, Defendants moved for a TRO and preliminary injunction.

58. On October 7, 2011, the District of Massachusetts court issued a temporary restraining order (“TRO”) enjoining Amphastar from selling enoxaparin pending a hearing on the motion for preliminary injunction. The court required Defendants to post a $50,000 bond for the TRO.

59. On October 28, 2011, the court issued a preliminary injunction to the same effect. The court required the Defendants to post a $100,000,000 bond for the preliminary injunction.

60. The Federal Circuit stayed the preliminary injunction on January 25, 2012 and vacated the wrongfully obtained preliminary injunction on August 3, 2012.

61. Defendants’ lawsuit prevented Amphastar from selling generic enoxaparin in the relevant market. From the issuance of the TRO until the Federal Circuit stayed the preliminary injunction on January 25, 2012, Amphastar was completely prevented from selling the drug enoxaparin. Even after the Federal Circuit vacated the preliminary injunction on August 3, 2012, Amphastar’s sales were considered “at risk” since final judgment based on the safe harbor provision of 35 U.S.C. § 271(e)(1) had

not yet happened, which prevented or impeded Amphastar from obtaining sales contracts it would have otherwise obtained.

62. During the time period in which Defendants wrongfully enforced the ’886 patent against Plaintiffs, obtaining first a TRO and then a preliminary injunction against the sale of enoxaparin by Plaintiffs, Defendants exercised extreme market power in the relevant market in the United States.

63. On July 19, 2013, the District Court of Massachusetts granted Amphastar’s motion for summary judgment, finding that Amphastar did not infringe the asserted claims of the ’886 patent under the Patent Act’s safe harbor provision, 35 U.S.C. § 271(e)(1). As a result of the judgment in the patent litigation against Defendants based on the safe harbor provision of 35 U.S.C. § 271(e)(1), Amphastar and a subsequent ANDA applicant, Teva, now have the ability to freely use the USP Method <207> for batch release testing for their generic enoxaparin. The price of generic enoxaparin has dropped as the result of natural competition, and to the benefit of consumers, including the state and federal governments.

COUNT 1

Violation of Section 1 of the Sherman Act

64. Each of the numerical paragraphs both above and in the following counts is incorporated herein by reference.

65. Defendants’ anticompetitive conduct set forth in this Complaint has violated Section 1 of the Sherman Act. *See* 15 U.S.C. § 1.

66. Defendants are separate and distinct entities; neither is a subsidiary or agent of the other. Apart from their agreement discussed herein, Defendants are economically independent from each other.

67. Defendants acted in concert during the proceedings before the USP.

68. On information and belief, Defendants entered into an agreement in restraint of trade in the United States.

69. On information and belief, Defendants conspired together to restrain trade in the United States.

70. Defendants behaved in a manner that unreasonably restrained trade in the United States.

71. Defendants affected interstate commerce by keeping the price of enoxaparin unreasonably high due to their wrongful restraint of trade.

72. As a result of being blocked from selling generic enoxaparin by Defendants' wrongful enforcement of their patent and TRO and preliminary injunction, Plaintiffs suffered antitrust injury. During the time Plaintiffs were blocked from selling enoxaparin to purchasers of enoxaparin and the general consuming public, including the state and federal governments, paid significantly higher prices than they would have paid had Plaintiffs not been blocked. As a result, Plaintiffs suffered numerous and significant damages, including but not limited to damaged reputation, reduced financing upon IPO, and lost profits on sales that they would have made but for the TRO and preliminary injunction.

73. As a result of Defendants' actions complained of herein, Amphastar has been damaged in an amount exceeding $75,000, the full amount of which remains to be determined.

COUNT 2

Violation of Section 2 of the Sherman Act

74. Each of the numerical paragraphs both above and in the following counts is incorporated herein by reference.

75. Defendants' anticompetitive conduct set forth in this Complaint has violated Section 2 of the Sherman Act. *See* 15 U.S.C. § 2.

76. Defendants wrongfully acquired monopoly power in the relevant market by deceiving the USP into adopting a standard test method that Defendants contended is covered by Defendants' patent rights. At the time of the anticompetitive acts complained of herein, the relevant product market was the market for generic enoxaparin, or in the alternative enoxaparin, and the relevant geographic market was the United States.

77. Defendants then used the wrongfully obtained monopoly to exclude Amphastar from the relevant market.

78. As a result of being blocked from selling generic enoxaparin by Defendants' wrongful enforcement of their patent and TRO and preliminary injunction, Plaintiffs suffered antitrust injury. During the time Plaintiffs were blocked from selling enoxaparin purchasers of enoxaparin and the general consuming public, including the state and federal governments, paid significantly higher prices than they would have paid had Plaintiffs not been blocked. As a result, Plaintiffs suffered numerous and

significant damages including but not limited to damaged reputation, reduced financing upon IPO and lost profits on sales that they would have made but for the TRO and preliminary injunction.

79. As a result of Defendants' actions complained of herein, Amphastar has been damaged in an amount exceeding $75,000, the full amount of which remains to be determined.

COUNT 3

Violation of Section 2 of the Sherman Act

80. Each of the numerical paragraphs both above and in the following counts is incorporated herein by reference.

81. Defendants conspired to monopolize in violation of 15 U.S.C. § 2.

82. Defendants are separate and distinct entities; neither is a subsidiary or agent of the other. Apart from their agreement discussed herein, Defendants are economically independent from each other.

83. Defendants had a specific intent to monopolize. Defendants specifically intended and effected through their willful deception of the USP to bar Plaintiffs from selling generic enoxaparin and did so by wrongfully pursuing a patent infringement action against Plaintiffs use of USP Method <207>.

84. Defendants made a conspiratorial agreement or overt act in furtherance of the ongoing conspiracy to monopolize through their patent infringement lawsuit filed on

September 21, 2011, which Defendants agreed to bring together as co-Plaintiffs, and did bring together as co-Plaintiffs.

85. Defendants committed further overt acts in furtherance of the conspiracy by seeking a TRO and a preliminary injunction in its lawsuit against Plaintiffs, both of which resulted in court orders that barred Plaintiffs from selling generic enoxaparin in the United States.

86. Defendants brought the patent infringement lawsuit and sought the TRO and the preliminary injunction with the specific intent to unlawfully maintain their monopoly. They intended these actions to result in court orders barring Plaintiffs from selling generic enoxaparin in the United States, with the result that Defendants would be the sole seller of generic enoxaparin in the United States.

87. As a result of being blocked from selling generic enoxaparin by Defendants' wrongful TRO and preliminary injunction, Plaintiffs suffered antitrust injury. During the time Plaintiffs were blocked from selling enoxaparin, purchasers of enoxaparin and the general consuming public, including the state and federal governments, paid significantly higher prices than they would have paid had Plaintiffs not been blocked. As a result, Plaintiffs suffered numerous and significant damages including but not limited to damaged reputation, reduced financing upon IPO, and lost profits on sales that they would have made but for the TRO and preliminary injunction.

88. As a result of Defendants' actions complained of herein, Amphastar has been damaged in an amount exceeding $75,000, the full amount of which remains to be determined.

COUNT 4

Violation of Section 2 of the Sherman Act

89. Each of the numerical paragraphs both above and in the following counts is incorporated herein by reference.

90. Defendants have attempted to monopolize the relevant market in violation of Section 2 of the Sherman Act based on the anticompetitive conduct described herein.

91. Defendants had a specific intent to monopolize the relevant market. As discussed in more detail above, Defendants specifically conspired to wrongfully block anyone else from selling generic enoxaparin in the United States. Defendants also specifically intended to monopolize the relevant market by barring Plaintiffs from selling generic enoxaparin through its wrongful lawsuit and injunction, which prevented Plaintiffs' sale of generic enoxaparin. In doing so, Defendants attempted to control high prices in the relevant market, and to exclude competition.

92. Through the anticompetitive and exclusionary acts described above, Defendants achieved a dangerous probability of success of monopolizing the relevant market. By excluding Plaintiffs, Defendants maintained their monopoly over generic enoxaparin in the United States. As a result, Defendants were able to charge a higher price for generic enoxaparin than if Defendants had not blocked Plaintiffs from selling generic enoxaparin.

93. The structure of the market in September 2011 created a dangerous probability of success for Defendants. In order to obtain FDA approval, any ANDA applicant would have to perform tests that Defendants said were covered by the '886 patent.

94. As a result of being blocked from selling generic enoxaparin by Defendants' wrongful TRO and preliminary injunction, Plaintiffs suffered antitrust injury. During the time Plaintiffs were blocked from selling enoxaparin, purchasers of enoxaparin and the general consuming public, including the state and federal governments, paid significantly higher prices than they would have paid had Plaintiffs not been blocked.

95. As complained of herein, Defendants' actions have damaged Plaintiffs in an amount exceeding $75,000, the full amount of which remains to be determined.

COUNT 5

Unfair Business Practices: Violation of CAL. BUS. & PROF. CODE § 17200

96. Each of the numerical paragraphs both above and in the following counts is incorporated herein by reference.

97. Defendants' actions as described in this Complaint constitute a violation of CAL. BUS. & PROF. CODE § 17200 because they are business practices that threaten to violate an antitrust law, violate the policy and spirit of an antitrust law, and otherwise significantly threaten or harm competition.

98. The preliminary injunction precluded Plaintiffs from advertising, offering for sale, or selling any of Plaintiffs' generic enoxaparin in the State of California.

99. As a direct result of Defendants' unfair business practices as stated herein, Plaintiffs have suffered injury in fact, including lost profits and other monetary damages, in excess of $75,000.

COUNT 6

Violations of the Cartwright Act, CAL. BUS. & PROF. CODE § 16700

100. Each of the numerical paragraphs both above and in the following counts is incorporated herein by reference.

101. Defendants acted as a trust pursuant to Section 16720 of the Cartwright Act, which defines "trusts" as a "combination of capital, skill or acts by two or more persons" for certain enumerated purposes.

102. Defendants created or carried out restrictions in trade or commerce to limit or reduce the sale of generic enoxaparin within the State of California.

103. Defendants prevented competition in the manufacturing, making, transportation, sale or purchase of generic enoxaparin within the State of California.

104. The actions of Defendants stated in the preceding paragraphs affected generic enoxaparin intended for sale, barter, use or consumption in the State of California.

105. As a direct result of Defendants' acts, Plaintiffs suffered injury in fact, including lost profits and other monetary damages, in excess of $75,000.

PRAYER FOR RELIEF

Wherefore Plaintiffs pray for the following:

A. Antitrust damages;

B. Punitive damages;

C. Treble damages;

D. Exemplary damages;

E. Unjust enrichment;

F. Lost profits;

G. Prospective damages;

H. Interest and costs;

I. Attorneys' fees; and

J. Such further relief as this Court may deem just and equitable.

DEMAND FOR JURY TRIAL

Pursuant to FED. R. CIV. P. 38, Plaintiffs hereby demand a trial by jury on its claims.

K&L GATES, LLP

Dated: September 17, 2015

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